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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,421	11/21/2003	John Eric Peckham	S63.2-11294-US01	3394

490 7590 06/30/2006

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

CHENG, JACQUELINE

ART UNIT	PAPER NUMBER
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3768

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,421	PECKHAM, JOHN ERIC	
	Examiner	Art Unit	
	Jacqueline Cheng	3768	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/05 10/04 3/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). Figure 20 as described in specification page 16 is missing.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-4, and 14** are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,165,194 (herein referred to as Denardo). Denardo discloses a wire which can be made from a stranded cable including one or more radiopaque strands, or which has radiopaque markers deployed along its length (col. 4 line 35-39). This continuous wire, seen in fig. 1, has a first portion that extends in a circumferential direction (element 12), a second portion that is in a

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longitudinal direction (element 14), a third portion extending circumferential (element 12), and then a fourth portion that extending longitudinally (element 14).

4. **Claims 1, 8, 9, 11, 14, 24, 26, and 36** are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,340,367 B1 (herein referred to as Stinson et al). Stinson et al. discloses a stent or stent-grafts (col. 12 line 8) delivery device having radiopaque markers on an implantable endoprosthesis having a tubular and radially expandable structure adapted to be disposed in a body lumen. As seen in figure 8 the radiopaque continuous wire (element 14) has a first circumferential direction, and a second longitudinal direction that can be disposed in a channel or lumen of the delivery device and exits out of a port. The wire marker is located about the rim of both the entry port and exit ports as seen in figure 8.

5. **Claim 37** is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,921,978 (herein referred to as Thompson et al). Thompson et al. discloses a catheter including a fluoroscopic marker to provide enhanced fluoroscopic visibility of the catheter. The marker is used to maneuver the catheter to a desired location and orientation (rotation) at a region of interest.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 5, 15-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Denardo.

The shape, size, and direction of the markers are design choices. The end portions of the marker in Denardo (element 16 in figure 1) can be used as a directional indicator pointing towards a particular end of the medical device. Having the directional indicator as an arrow instead of just a line, or to have the two ends of the wire to connect to create a directional arrow would be a design choice. It would also be a design choice as to how to place the marker wire so as that the distance between the end portions (element 22 in figure 1) is viewable over a certain degree of rotational range as well as the direction the markers should point. Denardo discloses that this gap can be changed to provide a wide variety of performance characteristics (col. 4 line 65-col. 5 line 7). US Publication No. 2002/0032432 A1 shows that having a marker in the shape of an arrow is known in the art. US Patent No. 5,921,978 discloses using markers to show a certain rotational degree range (col. 6 line 16-20).

8. **Claim 28, 30, 31-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. in view Thompson et al. Stinson et al. discloses the orientation of the marker wire as disclosed above. What Stinson et al. does not disclose is having a first marker appearing more visible than a second marker. Thompson et al. discloses having markers made of two different materials so that part of the marker provides a darker image and is more visible than the other part. It would be obvious to one with ordinary skill in the art at the time of the invention to

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combine Thompson et al. with Stinson et al. as both inventions are related to radiopaque marked medical devices.

9. **Claims 6-10, 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Denardo as applied to claim 1 above, and further in view of US Patent No. 6,264,671 B1 (herein referred to as Stack et al). Stack et al. discloses a deformable sheath attached to a catheter and introduced intravascularly to be expanded against an arterial wall. A stent is then deployed and can be expanded to a larger diameter by either inflating a balloon portion of the catheter or the stent can be of the self-expanding type (abstract, col. 1 line 49-51). To aid the physician to precisely position the catheter and sheath, radiopaque markers are disposed upon the catheter and sheath (col. 4 line 15-18). Although the markers are not in the specific pattern as disclosed in Denardo, it would be obvious to one skilled in the art to change the pattern of the radiopaque markers on the catheter and catheter sheath (of Stack et al) to any other pattern, such as the pattern of Denardo. It would be obvious to one with ordinary skill in the art at the time of the invention to combine Stack et al. with Denardo as both inventions are directed towards radiopaque marked intravascular procedures with stents.

10. **Claim 13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Denardo as applied to claim 1 above, and further in view of US Patent No. 6,574,497 B1 (herein referred to as Pacetti).

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. in view of Thompson et al. as applied to claim 28 above, and further in view of Pacetti.

Pacetti discloses passive markers for viewing catheters, implantable prostheses and stents under MRI (col. 3 line 53-60). Although the markers are not in the specific pattern as disclosed in Denardo, it would be obvious to one skilled in the art to change the pattern of the markers on the catheter and stents (of Pacetti) to any other pattern, such as the pattern of Denardo. It would be obvious to one with ordinary skill in the art at the time of the invention to combine Pacetti with Denardo and Pacetti with Stinson et al. and Thompson et al. because all the inventions are directed towards radiopaque marked intravascular devices.

11. **Claim 25 and 27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. as applied to claim 1 above, and further in view of US Patent No. 5,681,336 (herein referred to as Clement et al.).

Claim 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. in view of Thompson et al. as applied to claim 28 above, and further in view of Clement et al.

Clement et al. discloses a rotational ablation device for use in medical application particularly within blood vessels. The device can be provided with a radiopaque marker and it has a suction means to remove ablated lesion material from the body. It would be obvious to one with ordinary skill in the art at the time of the invention to combine Clement et al. with Stinson et al. and Thompson et al. as all the inventions because all the inventions are directed towards radiopaque marked intravascular devices.

Conclusion

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12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 5,425,709 discloses a sheath for a balloon dilation catheter.

Radiopaque markers are placed on the sheath and balloon catheter so that they can be fluoroscopically imaged for the surgeon to view the instruments.

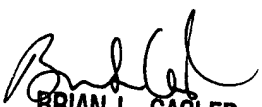
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596.

The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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